

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
_____	)	
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	
v.	)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8665

Bartle, J.

August 15, 2011

Angela K. Twete ("Ms. Twete" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,<sup>1</sup> seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").<sup>2</sup>

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with  
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To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney completes Part III if claimant is represented.

In August, 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Irvin F. Goldenberg, M.D., F.A.C.C. Dr. Goldenberg is no stranger to this litigation. According to the Trust, he has attested to at least 76 Green Forms on behalf of claimants seeking Matrix Benefits. Based on an echocardiogram dated December 5, 2001, Dr. Goldenberg attested in Part II of Ms. Twete's Green Form that she suffered from moderate mitral regurgitation and an abnormal left atrial

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2. (...continued)

serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

dimension.<sup>3</sup> Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$528,405.<sup>4</sup>

In the report of claimant's echocardiogram, the reviewing cardiologist, Azariah M. Kirubakaran, M.D., F.A.C.C., M.R.C.P., stated that claimant had "mild mitral regurgitation." Dr. Kirubakaran, however, did not specify a percentage as to the level of claimant's mitral regurgitation. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In February, 2004, the Trust forwarded the claim for review by Karen K. Hamilton, M.D., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Hamilton concluded that there was no reasonable medical basis for Dr. Goldenberg's finding that claimant had moderate mitral regurgitation because her echocardiogram demonstrated only mild mitral regurgitation. Dr. Hamilton explained that:

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3. Dr. Goldenberg also attested that claimant suffered from New York Heart Association Functional Class II symptoms. This condition, however, is not at issue in this claim.

4. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of the five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust does not contest the attesting physician's finding of an abnormal left atrial dimension, which is one of the complicating factors needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

Based on the single beat of color flow Doppler of the [mitral regurgitation] available to me on this study, the [mitral regurgitant] jet ratio came to only 16%. I don't know whether this is representative but it was all that was available on the tape. The [mitral regurgitant] jet gives the misleading appearance of filling more than 20% of the [left atrium] seen at the time the jet is seen. But that clip shows an off-axis view of the [left atrium] and underestimates its size at end systole. Of note, the records contain an [echocardiogram] report from 5/01 indicating trivial [mitral regurgitation]. And the report from the [physician] who originally read this [echocardiogram] is in the records and states mild [mitral regurgitation].

Based on Dr. Hamilton's finding that claimant had mild mitral regurgitation, the Trust issued a post-audit determination denying Ms. Twete's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.<sup>5</sup> In contest, claimant argued that there was a reasonable medical basis for Dr. Goldenberg's representation of moderate mitral regurgitation. In support, Ms. Twete submitted an affidavit of Dr. Goldenberg, wherein he stated:

The auditing [c]ardiologist, Dr. Karen Hamilton, states the patient's 12/05/2001 echocardiogram shows Mild Mitral Regurgitation. This is an erroneous finding

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5. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Twete's claim.

on the part of Dr. Hamilton. After re-review of Ms. Twete's 12/05/2001 echocardiogram, in my opinion, the study reveals Moderate Mitral Regurgitation.

Dr. Goldenberg also noted that Dr. Hamilton's report did not reference the still frames included with Ms. Twete's claim, which in his view, "illustrate moderate mitral valve regurgitation."

The Trust then issued a final post-audit determination, again denying Ms. Twete's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to Show Cause why Ms. Twete's claim should be paid. On May 20, 2005, we issued an Order to Show Cause and referred the matter to the Special Master for further proceedings. See PTO No. 5240 (May 20, 2005).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on May 26, 2006. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor<sup>6</sup> to review claims after the Trust and

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6. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance  
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claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Sandra V. Abramson, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant, and prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attending physician's finding that she had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Twete argues that her Green Form, Dr. Goldenberg's affidavit, and the still photographs provide a reasonable medical basis for Dr. Goldenberg's

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6. (...continued)  
of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.



representation that claimant had moderate mitral regurgitation.<sup>7</sup> Ms. Twete also asserts that the auditing cardiologist did not consider the still photographs in her evaluation because she did not list them as material she reviewed. Claimant further contends that the Trust has not offered any objective evidence to refute Dr. Goldenberg's "photographic based evidence," instead offering only Dr. Penkala's disagreement with Dr. Goldenberg. According to Ms. Twete, the Settlement Agreement and this court's prior decisions require a determination of the level of claimant's mitral regurgitation to be based on an echocardiogram conducted in accordance with the Feigenbaum and Weyman texts, using color flow Doppler rather than continuous wave Doppler. Ms. Twete also notes that eyeballing and inclusion of blue, in addition to green and mosaic, signals are appropriate. In addition, claimant asserts that the differences in the conclusions of the attesting physician and the auditing cardiologist are attributable to inter-reader variability, which claimant argues is "well-documented" in literature attached to her response. Finally, claimant analogizes the reasonable medical basis standard to a court's analysis of conflicting opinions offered by expert witnesses.

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7. Ms. Twete also asserts that the issue of reasonable medical basis should be controlled by the opinion of Gallagher v. Latrobe Brewing Co., 31 F.R.D. 36 (W.D. Pa. 1962). We repeatedly have rejected the Gallagher decision as controlling or persuasive. See, e.g., PTO No. 6275 at 9 (May 19, 2006).

In response, the Trust argues that the auditing cardiologist properly applied the reasonable medical basis standard. The Trust also asserts that inter-reader variability does not account for the difference between the conclusion of the auditing cardiologist and that of the attesting physician because Dr. Hamilton specifically determined that there was no reasonable medical basis for Dr. Goldenberg's findings. In addition, the Trust noted that, to the extent Dr. Goldenberg relied upon non-mosaic, laminar blue flow to support his finding, his methodology violates PTO No. 2640. The Trust further explained that claimant's attempt to analogize the reasonable medical basis standard to the analysis of conflicting expert opinions is misplaced because the reasonable medical basis standard is to be interpreted in the context of the Settlement Agreement. Finally, the Trust contends that Dr. Penkala reviewed claimant's entire echocardiogram, including the still photographs. According to the Trust, the still photographs do not establish a reasonable medical basis for Dr. Goldenberg's conclusion because they do not demonstrate a representative jet and do not include legible EKG readings sufficient to determine where in the cardiac cycle the supposed "jets" occurred.

The Technical Advisor, Dr. Abramson, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had moderate mitral regurgitation. Specifically, Dr. Abramson explained that:



It is an inappropriately abbreviated, incomplete study. In the parasternal long-axis view, there is trace mitral regurgitation. There are only 4 cardiac cycles obtained in the apical views and only one has color flow Doppler. Thus, it is impossible to determine a "representative" cardiac cycle since there is only one available. I measured the left atrial area of 21.8 cm<sup>2</sup> in a different cardiac cycle since the frame with the color flow imaging was angled to accentuate the mitral regurgitation, which cut off the left atrium. I measured this one mitral regurgitant jet area of 3.0 cm<sup>2</sup>. The RJA/LAA ratio = 14% which is consistent with mild mitral regurgitation. This one cardiac cycle at meter 16:07:26-16:07:27 is the same meter number [as] the four photographs that are submitted in the records.

In summary, the assessment of the severity of this claimant's mitral regurgitation is based on two cardiac cycles. Assuming they are representative cycles, this study demonstrates only mild mitral regurgitation. There is no reasonable medical basis for the Attesting Physician's claim that this patient has moderate mitral regurgitation. Angela K. Twete has only mild mitral regurgitation.

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. First, claimant does not adequately refute the findings of the auditing cardiologist or the Technical Advisor. Specifically, Ms. Twete does not directly confront the auditing cardiologist's determination that the mitral regurgitant jet "came to only 16%" or that "the [mitral regurgitant] jet gives the misleading appearance of filling more than 20% of the [left atrium] .... but that [the] clip shows an

off-axis view of the [left atrium]."<sup>8</sup> Ms. Twete also does not challenge Dr. Abramson's conclusion that the echocardiogram demonstrated an RJA of  $3.0\text{cm}^2$  and an LAA of  $21.8\text{cm}^2$ , resulting in an RJA/LAA ratio of 14%, "which is consistent with mild mitral regurgitation."<sup>9</sup> Neither Ms. Twete nor her attesting physician identified any particular errors in the conclusions of the auditing cardiologist or the Technical Advisor. Mere disagreement with the auditing cardiologist or the Technical Advisor without identifying any specific error by them is insufficient to meet a claimant's burden of proof.<sup>10</sup>

In addition, claimant's reliance on inter-reader variability to establish a reasonable medical basis for the attesting physician's representation that Ms. Twete had moderate mitral regurgitation is misplaced. The concept of inter-reader variability is already encompassed in the reasonable medical basis standard applicable to claims under the Settlement Agreement. In this instance, the attesting physician's finding of moderate mitral regurgitation cannot be medically reasonable

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8. As the Trust relied on this opinion in denying Ms. Twete's claim for Matrix Benefits, we disagree with claimant that the Trust did not refute Dr. Goldenberg's Green Form representation and still photographs.

9. Despite an opportunity to do so, claimant did not submit a response to the Technical Advisor Report. See Audit Report 34.

10. For this reason as well, we reject claimant's argument that Dr. Goldenberg's affidavit or the "analogous concept [of] admissibility of expert testimony" provides a reasonable medical basis for his Green Form representation that Ms. Twete suffers from moderate mitral regurgitation.

where the auditing cardiologist and the Technical Advisor specifically concluded that claimant's echocardiogram demonstrated an RJA/LAA ratio of 16% and 14%, respectively. Adopting claimant's argument would expand the range for moderate mitral regurgitation and would allow a claimant to recover Matrix Benefits when his or her level of mitral regurgitation is below the threshold established by the Settlement Agreement. This result would render meaningless this critical provision of the Settlement Agreement.

Finally, we reject claimant's argument that the still frames provided by Dr. Goldenberg provide a reasonable medical basis for his opinion. Dr. Abramson reviewed the still frames and determined that they demonstrated mild mitral regurgitation. In any event, we previously have stated that still frames alone are not sufficient to determine a claimant's level of mitral regurgitation. See, e.g., PTO No. 6897, at 7 (Jan. 26, 2007) (further citation omitted).

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of Ms. Twete's claim for Matrix Benefits.